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BY E-FILING

The Honorable Joseph J. Farnan, Jr.
United States District Court
844 King Street
Wilmington, DE 19801

Re: *The Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 04-940-JJF

Dear Judge Farnan:

This is in response to Mr. Fineman's letter to your Honor of July 6, 2007 (D.I. 107), with respect to the Federal Circuit's decision in *Takeda Chemical Indus., Inc. v. Alphapharm Pty., Ltd.*, No. 06-1329 (June 28, 2007). That case involved the obviousness of a chemical compound, "pioglitazone," in view of a structurally related compound, referred to in the opinion as "compound b." The Federal Circuit affirmed the district court's conclusion that the defendant had not demonstrated that pioglitazone was prima facie obvious.

The Federal Circuit noted that "Alphapharm's obviousness argument rested entirely on the court making a preliminary finding that the prior art would have led to the selection of compound b as the lead compound." (Slip op. at 16). The district court, however, rejected that argument and found as a fact that compound b would not have been a "lead compound" because the prior art did not suggest that it would be any more useful as a treatment for diabetes than a myriad of other compounds. In particular, the district court found "nothing in the prior art to narrow the possibilities of a lead compound to compound b." (*Id.*). The Federal Circuit held that this threshold finding was not clearly erroneous, and that pioglitazone was not prima facie obvious.

The rationale for the district court's "lead compound" finding in *Takeda* and its affirmance by the Federal Circuit does not apply here. The claims of P&G's '406 patent, in particular claim 15, made clear that 2-pyr EHDP was much more potent for the inhibition of bone resorption than any other compound known at the time. Resort to the specification of the '406 patent confirms the strikingly greater activity and better therapeutic ratio of 2-pyr EHDP compared to other known bisphosphonates. Thus, 2-pyr EHDP was certainly a lead compound.

In addition to its lead compound discussion, the Federal Circuit referred to the structural differences between the molecules of the two compounds. That discussion is not applicable here.

2-pyr EHDP and risedronate are isomers, and a comparison of their structural formulas shows that they are more closely structurally related than compound b and pioglitazone.

Teva remains available at the Court's convenience should the Court have any questions about this or any other aspect of the issues before the Court.

Respectfully submitted,

Karen L. Pascale (No. 2903)

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